MONDAY, 1/23! Fifth Annual Health Law Year in P/Review Conference

The Petrie-Flom Center's Fifth Annual Health Law Year in P/Review
Featured Panel: The End of ObamaCare? Health Care Reform Under A New Administration
Monday, January 23, 2017 8:30 AM - 5:00 PM
Wasserstein Hall, Milstein West AB Harvard Law School
1585 Massachusetts Ave., Cambridge, MA

LIMITED SEATS STILL AVAILABLE! REGISTER HERE.

Watch our social media for updates - including open seats - on Monday! And don’t forget, videos of the event will be posted on our website soon afterward.

The Fifth Annual Health Law Year in P/Review symposium will feature leading experts discussing major developments during 2016 and what to watch out for in 2017. The discussion at this day-long event will cover hot topics in such areas as health policy under the new administration, regulatory issues in clinical research, law at the end-of-life, patient rights and advocacy, pharmaceutical policy, reproductive health, and public health law.

See the full agenda with speakers here!

Read Faculty Director I. Glenn Cohen's blog post "The Best-Laid Plans For Health Care," the first in a series hosted by Health Affairs that will stem from the event.

This year's Health Law Year in P/Review is sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Harvard Health Publications at Harvard Medical School, Health Affairs, the Hastings Center, the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, and the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund.

NEW EVENT! Looking Forward: The Next Generation of Biosimilars

Looking Forward: The Next Generation of Biosimilars
February 7, 2017 12:00 PM
Wasserstein Hall, Milstein East A (2036)
1585 Massachusetts Ave., Cambridge, MA

Many of today's important medications are biological products made from living organisms, manufactured through biotechnology, derived from natural sources, or produced synthetically. Biosimilars are a type of biological product approved by FDA on the basis of being highly similar to an already approved biological reference product, like a generic drug. This panel of experts will discuss the current state of biosimilars in the healthcare ecosystem and what comes next from a technical and legal perspective. Topics include how the next generation of biosimilars
can improve patient access to standard-of-care therapies, the concept of "biobetters," economic and intellectual property considerations, and policy approaches to support existing and future biosimilars.

Panelists:

- Jennifer DiGiacinto, RRD International
- Robert S. Langer, MIT
- Benjamin Roin, MIT Sloan School of Management
- Moderator: Aaron Kesselheim, Harvard Medical School

This event is free and open to the public. Lunch will be provided.

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and Eagle Biologics.

VIDEOS NOW AVAILABLE! The Ethics of Early Embryo Research & the Future of the 14-Day Rule

The Ethics of Early Embryo Research & the Future of the 14-Day Rule
Conference held November 7, 2016

For over 35 years, the "14-Day Rule," prohibiting in vitro experimentation on embryos beyond 14 days, stood as an ethical line in the sand for embryo research around the world. Throughout the arc of the rule’s existence it had not been questioned, as scientists had been unable to grow embryos in vitro either up to, or beyond, 14 days; a practical limitation that served as a backstop to the ethical rule. However, in May 2016, labs in the U.S. and the U.K. were the first to report being able to sustain human embryos in vitro for up to 13 days. This development and other advances in in vitro research involving organized, embryo-like cellular structures raised a number of questions about the rule, its genesis, application, and future scope. This conference convened experts in bioethics, stem cell research, embryology, and law to discuss the ethical underpinnings and future scope of the rule. Questions discussed included:

- What are the historical, ethical and scientific rationales for establishing the 14-Day Rule?
- Should the 14-Day Rule be revisited in light of recent advances?
- Should the 14-Day Rule even apply to research involving the in vitro culture of embryo-like cellular structures?

A full agenda and all videos are available on our website. Check out some of the speakers’ slide presentations here!

This event was sponsored by the Harvard University Office of the Vice Provost for Research, the Edmond J. Safra Center for Ethics at Harvard University, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, and the Harvard Stem Cell Institute, with support from the International Society for Stem Cell Research and the Center for Bioethics at Harvard Medical School.

Scholarship from Petrie-Flom Affiliates

The Promise and Peril of Emerging Reproductive Technologies
by I. Glenn Cohen (Faculty Director), George Q. Daley, and Eli Y. Adashi
Science Translational Medicine, Vol. 9, Issue 372 (2017)
Public Engagement, Notice-and-Comment Rulemaking, and the Common Rule
by Holly Fernandez Lynch (Executive Director) I. Glenn Cohen (Faculty Director), and Barbara E. Bierer

Regulating Secrecy
by W. Nicholson Price II (Academic Fellow Alumnus)

Promoting healthcare innovation on the demand side
by W. Nicholson Price II and Rebecca S. Eisenberg
Journal of Law and the Biosciences, January 16, 2016 (online)

Federal Circuit Court Appeal Cites Rachel E. Sachs
By Paul D. Clement et al., citing work by Rachel E. Sachs (Academic Fellow Alumna)

News from Petrie-Flom Affiliates

New rules ease consent requirements for scientists using patient specimens
By Sharon Begley, quoting Holly Fernandez Lynch (Executive Director)
STAT, January 18, 2017

A New Fertility Technique Could Make 'Designer Babies' a Reality
by Kristen V. Brown, quoting I. Glenn Cohen (Faculty Director)
Gizmodo, January 13, 2017

New fertility procedure may lead to 'embryo farming', warn researchers
by Ian Sample, quoting I. Glenn Cohen
The Guardian, January 11, 2017

Babies made without mothers 'will come sooner than we think', leading scientists warn
by Mia De Graaf, quoting I. Glenn Cohen
Daily Mail, January 11, 2017

Eggs from Skin Cells? Here's Why the Next Fertility Technology Will Open Pandora's Box
by Emily Mullin, quoting I. Glenn Cohen
MIT Technology Review, January 11, 2017

Babies born without mothers is not science fiction but the future, suggest scientists
by Rachel Roberts, quoting I. Glenn Cohen
The Independent, January 13, 2017

Discussion of ethics of new IVG technique is needed, say US experts
FDA Further Explains Delay on LDT Guidance
By Zachary Brennan, quoting Rachel E. Sachs (Academic Fellow Alumna)
Regulatory Affairs Professionals Society, January 13, 2017

Regeneron CEO: Amgen's disruptive Praluent-blocking patent move hurts patients
by Carly Helfand, quoting Rachel E. Sachs
FiercePharma, January 10, 2017

Could Amgen's Patent Victory Be Bad For Medicine?
by Matthew Herper, quoting Rachel E. Sachs
Forbes, January 6, 2017

Recent Blog Posts

General health law/policy:

- "Public Variant Databases: Data Share with Care," by Adrian Thorogood
- "Maybe For-Profit Hospitals Aren't So Bad," by Shailin Thomas
- "The Ill-Designed "Continuous Treatment" Rule for the Health Law of Massachusetts," by Alex Stein
- "Housing Equity Week in Review," by Center for Public Health Law Research
- "The Unhealthy Return to Individual Responsibility in Health Policy," by Allison Hoffman
- "Final Common Rule Revisions Just Published," by Holly Fernandez Lynch
- "Well-rested versus well-trained doctors: New twist in debate over resident duty hours (Part II)," by Brad Segal
- "Congressional Ignorance and the OTA," by Seán Finan

Health care reform/finance:

- "Is Mike Pence's Medicaid Expansion a Blueprint for Donald Trump's Health Care Reform?," by David Orentlicher
- "Over Before It Started: CMS Abandons New Payment Pilot," by Zack Buck

Pharmaceuticals:

- "Let's All Worry About The Effects of Patent Injunctions Against Drug Manufacturers," by Rachel Sachs

'The Week in Health Law' podcasts:

- "Tim Jost on 'The Week in Health Law' Podcast," by Nicolas Terry and Frank Pasquale

Petrie-Flom Center Events

Check out our website for a more complete listing of events as well as full co-sponsorship information about our collaborators. Remember, you can find materials from many of our events, including slide presentations and full event videos, online in our events archive.
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February 7, 2017 12:00 PM
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REGISTRATION REQUIRED! Returning Results to Research Participants: A Health Policy and Bioethics Consortium
February 10, 2017 12:30 - 2:00 PM
Wasserstein Hall, Milstein East C, Harvard Law School, 1585 Massachusetts Ave., Cambridge, MA

Yuval Noah Harari in conversation with Michael Sandel - A discussion of Harari’s new book Homo Deus: A Brief History of Tomorrow
February 22, 2017 6:00 PM
Brattle Theater, 40 Brattle St., Cambridge, MA

AGENDA AVAILABLE! 2017 Petrie-Flom Center Annual Conference: Transparency in Health and Health Care: Legal and Ethical Possibilities and Limits
April 28, 2017
Wasserstein Hall, Milstein East ABC (2036), Harvard Law School, 1585 Massachusetts Ave., Cambridge, MA

Health Policy and Bioethics Consortia

- Returning Results to Research Participants
  February 10, 2017
- Promoting Accurate and Useful Public Reporting on Physicians
  March 29, 2017

Other Harvard Events

Harvard Medical School 2017 Bioethics Conference: The Ethics of "Making Babies"
April 28, 2017
Harvard Medical School, Boston, MA

Health Law Policy & Bioethics Workshops
The 2016-2017 *Health Law Policy, Biotechnology, and Bioethics Workshops* provide a forum for discussion of new scholarship in these fields from the world's leading experts. Harvard graduate students may register to take the workshop for course credit, but it is also open to the public.

This year, the workshop is led by Professor I. Glenn Cohen, and meets on selected Monday evenings from 5-7 PM on the Harvard Law School campus. The invited presenter generally speaks for about 30 minutes, after which the floor is opened for Q&A. It is recommended to read the papers in advance. Papers will usually be posted on the website one week before they are scheduled for presentation, but occasionally are available by request only.

Questions about the workshop should be directed to Jennifer Minnich (minnich@law.harvard.edu).

Upcoming workshops include:

**February 13:** Brendan Maher, University of Connecticut School of Law  
**March 6:** Khiara Bridges, Boston University School of Law  
**March 27:** Kathryn Zeiler, Boston University School of Law  
**April 10:** Leo Beletsky, Northeastern University School of Law  
**April 17:** Judith Daar, Whittier Law School

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**Harvard Opportunities**

**Call for Abstracts: Harvard Annual Bioethics Conference The Ethics of "Making Babies"**  
Harvard Medical School Center for Bioethics  
**Application Due: January 31, 2017**

**Fellowship in Bioethics, 2017-2018**  
Harvard Medical School Center for Bioethics  
**Application Due: March 6, 2017**

**Postdoctoral Research Scholars Program in Bioethics**  
Harvard Medical School Center for Bioethics  
**Application Due: March 31, 2017**

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**Other Opportunities**

All opportunities are posted once in our newsletter. For the full posting and for other available positions, please visit our website.

**Call for Applications: International Bioethics Summer School**  
Global Bioethics Initiative (GBI)  
**Application Due: Rolling Admissions, Early Registration Deadline April 15, 2017**

**Clinical Ethics Faculty (open rank)**  
The Center for Medical Ethics and Health Policy, Baylor College of Medicine  
**Application Due: February 17, 2017**

**Quantitative Research Associate**  
The Center for Medical Ethics and Health Policy, Baylor College of Medicine  
**Application Due: Open until filled.**

**Project Leader, Academic and Clinical Programs**  
The Center for Medical Ethics and Health Policy, Baylor College of Medicine  
**Application Due: Open until filled.**
Research Coordinator
The Center for Medical Ethics and Health Policy, Baylor College of Medicine
Application Due: Open until filled.

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